

UCLA-UCI Alpha Stem Cell Clinic (ASCC) Consortium

Grant Award Details

UCLA-UCI Alpha Stem Cell Clinic (ASCC) Consortium

Grant Type: Alpha Stem Cell Clinics

Grant Number: AC1-07675

Project Objective: To accelerate the conduct of high quality stem cell clinical trials by providing clinical operations

support, development and provision of accelerating resources and tools and by leveraging the

assets and aggregated value of the Alpha Clinics Network.

Investigator:

Name: John Adams

Institution: University of California, Los

Angeles

Type: PI

Disease Focus: Immune Disease, Pediatrics

Human Stem Cell Use: Adult Stem Cell

Award Value: \$8,000,000

Status: Active

Progress Reports

Reporting Period: Year 1

View Report

Reporting Period: Year 2

View Report

Reporting Period: Year 3

View Report

Grant Application Details

Application Title:

Alpha Stem Cell Clinic (ASCC) Consortium

Public Abstract:

Two world renowned research universities with their regional partners will join forces to create the CIRM Alpha Stem Cell Clinic (ASCC) Consortium. We are uniquely qualified by our respective institutional knowledge and collective experience to establish best practices for the delivery of stem cell therapies and education as we combine: 1) world class state-of-the-art medical centers and related health-care systems; 2) highest caliber stem cell research and education; 3) long established and successful gene medicine programs; and 4) robust and varied clinical trial infrastructure.

Our institutions provide the best in healthcare and the latest in medical technology. We are located in neighboring counties that together constitute ~34% of the total California population giving the ASCC access to a significant socially, economically and ethnically diverse population. The ASCC will employ a mobile model of management for the in- and out-patient operations, linking the institutions with their affiliated clinical care facilities, thus permitting the multi-directional flow of resources, personnel and study subjects.

The ASCC includes significant institutional commitments that will leverage substantial existing infrastructure to ensure its long term sustainability:

- NIH-funded Clinical and Translation Science Awards (CTSAs).
- A powerful consortium that provides:
- o On-line central IRB review,
- o Clinical Trials Management System,
- o Biobank and processing labs,
- o Sophisticated informatics to identify the best qualifying subjects, in an IRB-compliant manner, from among the 2M patients in the care system,
- o Drug and Device Discovery and Development initiative focusing on the early translation of academic discovery into valuable and impactful therapies.
- History of translating scientific discoveries to ground breaking clinical therapies including decades-long track record of successful GMP manufacturing and delivery of novel gene/cell therapies, notably the only FDA approved hESC based clinical trials accruing subjects.
- Stem Cell Research Centers provide critical state-of-the-art resources, dedicated, trained, technical staff, and GMP level human pluripotent stem cell derivation laboratories and banks as well as other cutting edge critical core resources,
- Exemplary education and public outreach programs to address the unique challenges of stem cell medicine.

Our lead clinical trials will develop multi-use platforms that can be used to deliver cell therapeutics across multiple trials (e.g., gene transfer and engineered immunity), providing new therapies for a wide range of life-threatening diseases.

The ASCC is built on 3 central principles: 1) commitment to the development of platforms using stem cells for multiple therapies; 2) training the next generation of stem cell scientists in the use of the platforms; and 3) using intra-and extra-institutional resources to rapidly move the most promising discoveries from the laboratory to clinical trials.

California:

Statement of Benefit to Two world renowned research universities and our regional partners will join forces to create the CIRM Alpha Stem Cell Clinic (ASCC) Consortium. The ASCC will be a center of excellence for the development and delivery of stem cell therapies, accelerating the availability of treatments to the population of California. We are uniquely qualified by our respective institutional knowledge and collective experience as we combine:

- World class medical centers and related health-care systems;
- Highest caliber stem cell research and education;
- Long established and successful gene medicine programs; and
- Robust and varied clinical trial infrastructure.

We are located in neighboring counties that together constitute ~34% of the total California population representing a significant socially, economically and ethnically diverse population. The ASCC will maximize availability of our clinical trials through a mobile model of in- and out-patient operations that permits the multi-directional flow of resources and personnel in the service of a range of patients from those entering Phase I clinical trials to those seeking FDA approved treatments.

The ASCC will provide the foundation for our lead clinical trials to deliver new cell therapies for cancer and blood diseases. Our lead clinical trials developed multi-use platforms that, if successful, will be used to deliver cell therapeutics across multiple trials (e.g., gene transfer and engineered immunity), providing new therapies for a wide range of life-threatening diseases in children and adults, including genetic disorders (e.g., sickle cell disease), HIV/AIDS, and many forms of cancer.

The ASCC will provide the necessary infrastructure and medical and operational expertise to effectively and efficiently drive novel stem cell therapies to clinical trials and ultimately change clinical practice. We will achieve 6 goals:

- Create a center of excellence for cell-based therapies, addressing the unique challenges of testing and delivering novel products by integrating and building upon our extensive experience and many strengths;
- Build interactive and highly trained teams and electronic data sharing systems to accelerate and translate discovery to improve human health;
- Transform the delivery of cell therapeutics through our proven GMP manufacturing;
- Advance, expand, and integrate the educational opportunities that informs patients, families, communities, and clinicians of the full range of scientifically sound and medically appropriate, regulated stem cell-based clinical trials while providing objective information about potentially dangerous and unproven procedures;
- Identify and promote technologies for the rapid commercialization of promising new therapies, consistent with the CIRM mission to provide return on investment to the state, and
- Serve as a regional, national and international resource for evidence-based best practices in stem cell treatments.

Source URL: https://www.cirm.ca.gov/our-progress/awards/ucla-uci-alpha-stem-cell-clinic-ascc-consortium